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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/067,570 | 02/05/2002 | Carl A. Schu | P-9201.02 | 5843 |

27581 7590 10/05/2005

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| EXAMINER | |
|---|---|
| EVANISKO, GEORGE ROBERT | |
| **ART UNIT** | **PAPER NUMBER** |
| 3762 | |

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/067,570 | SCHU ET AL. | |
| | Examiner | Art Unit | |
| | George R. Evanisko | 3762 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *16 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *25-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/16/05 has been entered.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 25, 29 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blaser (4202341). Blaser discloses the claimed invention having a cardiac sense electrode (the claimed physiological sensor), a signal processor of self timed logic elements in a chain to

process the signal, elements 2, 3, and 4, an operating system of logic circuits to generate a therapy trigger signal, elements 5 and 6, and therapy delivery means, elements 13 and 14 operating without contemporaneous storage of physiological signals from the sensor and signal processor, except for the operating system being at least one integrated circuit. In addition, for claim 34, the system of Blaser is capable of meeting the functional use recitations of the processed signal relating to one of ischemia, arrhythmia, or a change in cardiac output since his system processes all cardiac signals and is used for irregular heart rhythms (arrhythmia). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pacer system as taught by Blaser, with the operating system being at least one integrated circuit since it was known in the art that pacemakers have circuits and operating systems be at least one integrated circuit to reduce power consumption, size, and capacitance.

Claims 26, 27, 28, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blaser. Blaser discloses the claimed invention using and the use of a ventricle controlled and/or auricle controlled pacemaker (column 17, lines 50-64) and therefore would inherently contain two electrodes since an electrode would be needed for each chamber (in the alternative, see the rejection below). But Blaser does not disclose the sensor being electrodes, an activity sensor, or a blood pressure (or intra cardiac pressure), temperature, pH, or gas concentration sensor. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pacer system as taught by Blaser, with a sensor being electrodes, an activity sensor, or a blood pressure (or intra cardiac pressure), temperature, pH, or gas concentration sensor since it was known in the art that pacer systems use a sensor being electrodes to provide a bipolar, localized signal from the particular organ so as not to receive interference from other

signals in the body and since it was known in the art that pacer systems use an activity sensor or a blood pressure, temperature, pH, or gas concentration sensor to provide an alternate conventional sensor that senses the heart beating, a sensor that can be located in a different part of the body, and/or a signal to the pacer system to allow the system to determine when cardiac therapy is needed.

Claims 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blaser.

Blaser discloses the claimed invention except for the system including a telemetry circuit for wirelessly communicating an IMD operating parameter to a remote circuit, a memory activation means for causing storage of a temporal portion of the cardiac and physiological signals, and a memory for recording a temporal portion of the signal. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable system as taught by Blaser, with a telemetry circuit for wirelessly communicating an IMD operating parameter to a remote circuit, a memory activation means for causing storage of a temporal portion of the cardiac and physiological signals, and a memory for recording a temporal portion of the signal since it was known in the art that implantable systems use: a telemetry circuit for wirelessly communicating an IMD operating parameter to a remote circuit to allow a physician to look at the cardiac data and adjust the therapy and the IMD; a memory activation means for causing storage of a temporal portion of the cardiac and physiological signals to allow the patient to record cardiac and physiological signals when the patient thinks he is experiencing an arrhythmia so a doctor can look at the data; and a memory for recording a temporal portion of the signal to allow the data to be evaluated at a later date by a physician.

### *Response to Arguments*

Applicant's arguments filed 8/16/05 have been fully considered but they are not persuasive. The argument that "Blaser is devoid of any mention or use of the terms sensor, sense, sensing, and that Blaser describes only traditional cardiac pacing and sensing via electrodes is not persuasive since Blaser senses the cardiac output, since the applicant argues that Blaser describes only traditional cardiac pacing and sensing (which is a sensor and does sensing), and since the applicant claims the sensor is traditional cardiac sensing electrodes in claims 26 and 27. The argument that the Examiner ought to present evidence to support the conclusion of obviousness is not persuasive since the record contains numerous documents to show that the elements recited (IC circuitry, electrodes, activity sensors, etc) in the 103 rejections are well known in the art and since the Examiner discussed the documents in the final office action of 5/16/05. The record contains several cited references in the specification and IDS, such as 5916237, 4561442, 4515159 (IC operating system) and 5388578 and 5154170 (bipolar electrodes and activity sensor), in addition to the applicants own Background section, which teaches the elements to be well known in the art.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

George R Evanisko
Primary Examiner
Art Unit 3762

10/3/5

GRE
October 3, 2005